IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Inventor: Patrick Guiney App. No.: 10/712,280 Filing Date: November 12, 2003 Title: SPECIMEN FILTER CONTAINER HAVING DATA STORAGE	Examiner: Hyun, Paul Sang Hwa Art Unit: 1743 Docket No. 11.037011 US Confirmation No. 9311

SUPPLEMENTAL DECLARATION OF PATRICK GUINEY UNDER 37 C.F.R. §1.131

Mail Stop After Final
Commissioner for Patents
Box 1450
Alexandria, Virginia 22313-1450

Commissioner:

I, Patrick Guiney, hereby declare as follows:

1. I am named as an inventor in the above-identified application.

2. I was employed by Cytyc Corporation ("Cytyc") when the above-identified application was filed, and I am currently employed by Cytyc.

3. Prior to August 26, 2003, while employed by Cytyc, I prepared laboratory notebook entries entitled "ROM Slide Prep for Multiple Test Types" (redacted copies of which are attached hereto as Exhibit A).

4. Each page of the laboratory notebook (Exhibit A) bears my signature and a date prior to August 26, 2003.

5. Prior to August 26, 2003, and following preparation of my laboratory notebook entries, I prepared an invention disclosure entitled "ROM Slide Preparation" (a redacted copy of which is attached hereto as Exhibit B), which I submitted to Cytyc's patent department.

6. My understanding is that the patent department assigned number 03-017 to my invention disclosure, and that prior to August 26, 2003, Mark Casey, Chief Patent Counsel of Cytyc, sent the invention disclosure together with a letter to Bingham McCutchen requesting that Bingham McCutchen file a patent application for my invention pending the outcome of a patentability search, as reflected in the letter identifying invention disclosure number 03-017 and corresponding patent application reference number 11.037011 (a redacted copy of the letter is attached hereto as Exhibit C).

7. I then received and reviewed the 11.037011 patent application, which was e-mailed to me by Gary Lueck, a patent attorney then employed by Bingham McCutchen. My understanding is that the patent application was thereafter filed on November 12, 2003, following my review and approval of the specification.

9. All statements made herein of my own knowledge and true and all statements made on information and belief to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 10/16, 2008

Patrick Guiney

Exhibit A - B
ANNOTATED

Title: ROM Slide Prep for Multiple Test Types

Idea: Encode lot specific parameters for liquid-based cytology filters into a read-only-memory (ROM) chip to customize and optimize slide preparation sequence for multiple test types. 1, 18, 51, 52

19

How would ROM slide prep would work?

- Packaging for multiple filters would include a ROM chip programmed with lot-specific parameters. 19, 35
- Individual filters would be labeled or printed with a barcode to indicate lot number, expiration date and test type. 51, 52, 54

39

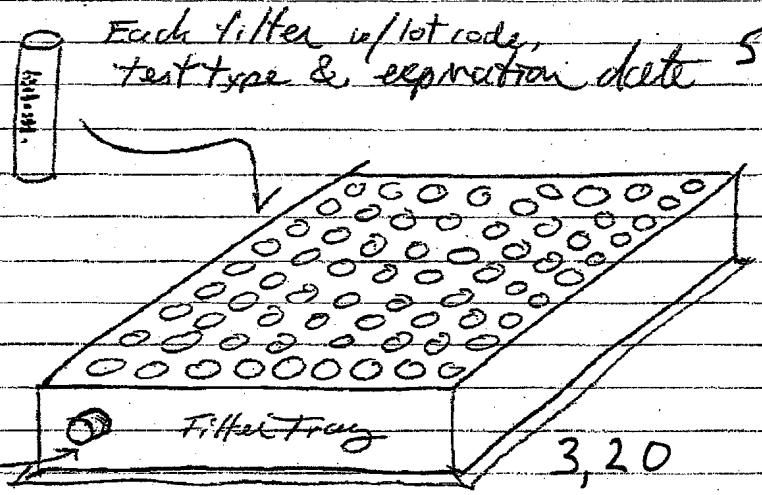
- Sample vials would be labeled or printed with a barcode to indicate lot number, test type and possibly expiration date 54
- The slide processor would have an electronic interface to read the ROM chip memory and electro-optical interfaces to read the information on the filters and sample vials. 18, 52, 19, 39
- Before processing the sample, the slide processor would verify test type and valid lot expiration (future date) for the filters and sample vials. 18, 52, 19, 53, 12, 31

54

Read and understood by me Lee P. Wade Date

Title: ROM Slide Prep for Multiple Test Types (continued)

- If the test type of the filter matches the sample vial and the lot codes have not expired, the
18,52 slide processor will proceed with the sample processing and slide preparation per the parameters and sequence encoded into the ROM.
- Data within the ROM would be encrypted for security and stored with a cyclic-redundancy-code (CRC) as a means to verify data integrity.



Two terminal ROM interface 18 protrudes from one side of filter tray such that terminals mate properly to slide processor interface. If possibly should be mechanically keyed to prevent mis-insertion

3,20

Sample vial 54 with lot code, test type and possibly expiration date

Read and understood by me Joel E. Wolpe Date

Exhibit B

Cytyc Invention Disclosure

DISCLOSURE #:	
Date Received:	
Author:	

TITLE	DATE
ROM Slide Preparation	

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Signature and Date

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E-mail:

Signature and Date

WITNESS
(Read & Understood)

Name:
Phone:

Signature & Date

ABSTRACT & FIGURES
(General description of the idea as it relates to the present state of the art.)

Encode lot-specific parameters for liquid-based cytology filters into a read-only-memory (ROM) chip to optimize slide preparation on a lot-by-lot basis and to adapt processing sequence or parameters for multiple test types. The idea includes the following elements:

- Packaging for multiple filters would include a ROM chip programmed with valid test types, associated process sequence parameters, lot specific parameters and lot expiration dates.
- Individual filters would be labeled or printed with a machine-readable code (e.g. barcode) to indicate lot number and test type.
- Sample vials would be labeled or printed with a machine-readable code (e.g. barcode) to indicate lot number, test type and sample expiration date.
- The slide processor would have an electronic interface to read the ROM memory chip contents and electro-optical interfaces to read the codes on filters and sample vials.
- Before processing the sample, the slide processor would verify test type compatibility and valid expiration dates for the filter and sample.
- If the test type of the filter matches the sample vial and the filter lot code and sample have not expired, the slide processor will proceed with the sample processing and slide preparation per the parameters encoded into the ROM.
- Data within the ROM would be encrypted for security and stored with a cyclic-redundancy-code (CRC) as a means to verify data integrity.

The idea provides the following benefits:

- Reduce risk for operator error:
  - Automatically reject expired lots of materials and expired samples
  - Automatically verify matching filter and sample types for many different types of samples and filters
- Improved slide processing capability and consistency by counteracting lot-to-lot variation of filters
- Adaptation of the process sequence and parameters to process slides for different samples and test types (e.g. GYN, non-GYN, ductal lavage, etc.)
- Provides capability to add new processing sequences to existing slide processors without need to upgrade processor software or hardware

Keywords: ROM, Slide Preparation, Cytology

GENERAL INFORMATION

Documentation of Idea:

321	6-	
Lab Notebook No.	Page No.	Other:

Has the idea been discussed with anyone outside of Cytyc, if so to whom, how, and when. Please contact Mark Casey at x3309 to discuss any previous disclosures.

No

Is there a planned disclosure of this idea via publication of a paper, meetings with non-Cytyc, showing of prototypes at tradeshows, etc. If so, provide details. (Who, when, where, etc.)

No

Project Name and/or Number: ROM Slide Prep

Project Phase (e.g. concept, research, development, validation, scale up, etc.): Concept

Product association (e.g. TP2000, vial, PreservCyt, etc.): TP2000, TP3000, Filters, Sample Vials,

Product release date: Products listed above are already released.

BACKGROUND
Describe the present state of the art related to your idea including any existing devices, therapies, applications, manufacturing processes, or any known patents, articles, etc.

18, 29, 52 ↓

At this time, there are three liquid-based, thin layer slide processor systems; ThinPrep 2000 by Cytyc, ThinPrep 3000 by Cytyc and the PrepStain by TriPath.

On the ThinPrep 2000 keypad, operators may select and initiate one of four slide-processing sequences; one sequence for gynecologic (GYN) or three sequences for non-gynecologic (non-GYN) samples. The non-GYN filters are blue to help operators visually differentiate the clear plastic filters required for GYN sample types. The ThinPrep 2000 processor does not automatically discriminate filter types or sample types. Both types of filters and sample vials have the same physical form factor and may be incorrectly processed via operator error. The slide processor does not read lot numbers or expiration dates so the ThinPrep 2000 processor will not reject expired lots of filters or sample vials. The process sequence and parameters embedded in the ThinPrep 2000 slide processor will not automatically adapt to different lots of filters or different sample types.

The ThinPrep 3000 processor is limited to one slide processing sequence for batches of GYN samples. Multiple sample types are not supported although the processor does have a color sensor to detect and reject the blue filters intended for processing non-GYN samples. The ThinPrep 3000 slide processor does not read lot numbers or expiration dates and will not reject out of date filters or samples. Likewise, the ThinPrep 3000 will not automatically optimize or adapt slide processing for different lots of filters or different types of samples.

The Tripath PrepStain system processes GYN samples exclusively and does not read lot numbers or expiration dates. The PrepStain processor will not reject out of date materials or samples and will not automatically adapt to different lots of filters or different types of samples.

In summary, the present state of the art is that slide processors do not automatically differentiate or adapt to materials consumed during slide preparation. The ThinPrep 2000 has limited capability to process four types of samples (1 GYN and 3 non-GYN) but there is significant risk of operator error. The ThinPrep 3000 and Tri-path PrepStain process slides for GYN samples exclusively. There is additional risk for operator error with all the slide processors in that operators must visually verify that lots of materials or samples have not expired.

PREFERRED EMBODIMENTS
In detail, please describe the specific features of your idea including, design, applications, operation, process, materials, coatings, and method of use and manufacture. Please attach any relevant figures, sketches, diagrams, CAD drawings, notebook pages, and any other supporting material that supplements your idea/invention. Please include an index of figures if necessary.

Lot specific information to be stored in ROM will include:

51, 52, 53

Data or Parameter	Number of Bytes	Comments
Filter Lot Code	12	Up to 24 digits of lot code including means to verify expiration
Compatible Test or Sample Types	10	Any combination of up to 80 filter or sample types (1 bit each) including GYN, Superficial, Fluids & FNA, Mucoid, etc.
Number of Slide Process Steps	1/2	Specify up to 32 process steps to process slide for test type
Process Step Variable Parameter Data	480	Allow up to 15 bytes to specify variable parameter data (e.g. time, pressure, level, distance, temperature compensation, voltage, current, etc.) for each of up to 32 process steps
ROM Registration Number	8	Unique 64 bit registration number to assure trace-ability of individual ROMs
Cyclic Redundancy Check (CRC)	2	To verify data integrity
Encryption Key	16	Encrypt ROM data for security and to prevent tampering
Total Requirement (bytes)	529	

12, 31

21, 30, 43

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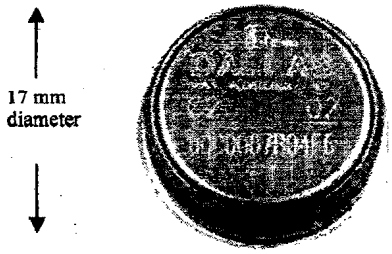
35, 51, 52, 55

ROM Memory Chip Component:

From the data requirements shown above, 16 kbit (2k byte) EPROM chips would provide adequate memory with excess capacity to include data for up to four different types of filters. The idea requires a physically small package and serial data interface to achieve both cost and space efficiency. The DS1985 iButton is a low cost memory device manufactured by Dallas Semiconductor that provides 16 kbit EPROM memory in a small, durable (stainless steel) package with interface to data, power and programming signals via a single (1 wire) connection. Each DS1985 EPROM provides a unique ROM Registration number (64 bits) for absolute trace-ability and options for permanent write-protection to prevent corruption of data.

6, 23



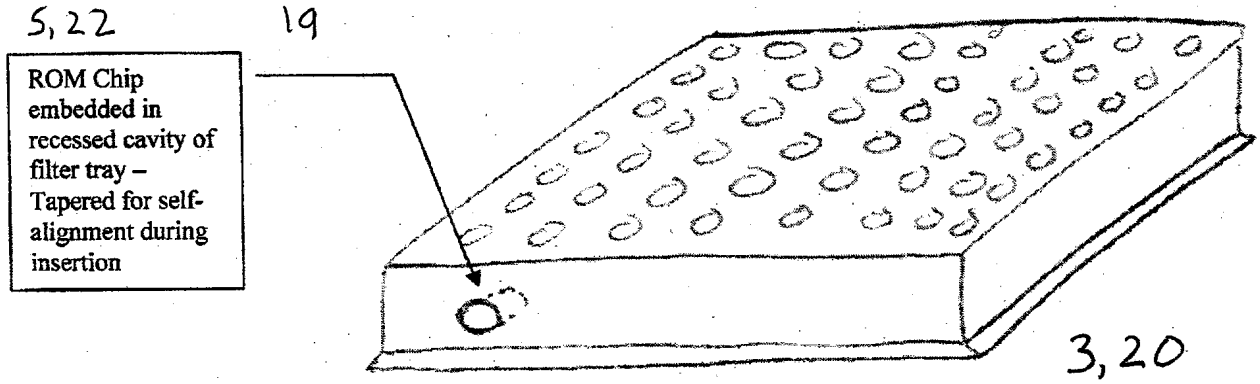
Filter Packaging for ROM Memory Chip: 5, 22 ↙ 41

One side of a filter tray would house a ROM chip in a recessed cavity with two electrodes (one reference and one signal). The electrodes in the recessed cavity would mate with two corresponding interface electrodes in the slide processor.

29 For batch processors that accept one or more filter trays, the male (processor) to female (filter tray) interface would mechanically limit proper tray insertion to only one of the four possible orientations. Slide processor latches for securing the filter tray would not close fully unless the ROM is properly interfaced to prevent operators from prematurely initiating slide processing. The male and female sides of the mechanical interface would be appropriately tapered to lead in and self-align the interface electrodes during insertion. 37 ↓

An additional filter packaging requirement for batch processors would be pre-determined tray locations for different types of filters. Pre-defined filter locations will allow the slide processor to locate and retrieve different types of filters as necessary to process different types of samples.

Slide processors that require manual loading of materials for each slide would include a wand interface for reading the ROM. The wand would provide the male side of the mechanical interface. A short cable (approximately 3 feet) would link the wand to the slide processor. Operators would briefly insert the wand into the filter tray once before using the first filter from a new filter tray. In response, the slide processor would audibly beep to indicate valid data acquisition of the ROM memory contents.



Slide Processor Functionality with ROM: 5, 22

53 ↓

Upon insertion of a filter tray with a ROM chip, the slide processor would execute the following steps: 29

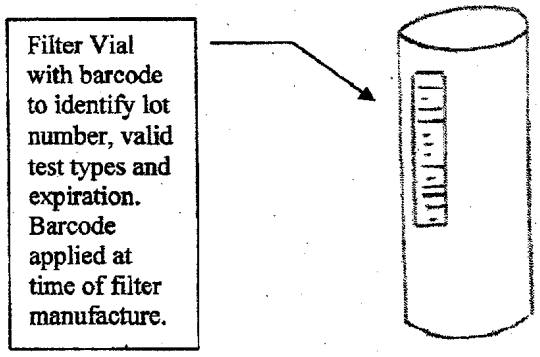
1) Establish serial data communication with ROM chip 36
2) Read contents of ROM chip into slide processor 18, 52
3) Verify CRC for data integrity,
4) Decode encrypted data with key
5) Save lot specific information including lot codes, valid test or sample types, number of process steps, variable parameter data, ROM registration number and CRC for subsequent sample and slide processing

41

After reading, verifying and decoding the ROM data from one or more filter trays, the slide processor would process subsequent samples in the following manner

1) Read sample lot code, verify expiration, record patient number
2) Locate appropriate filter for sample type from pre-determined location in tray 3, 20
3) Read filter lot code, verify matching filter & sample test types, verify expiration
4) Determine appropriate process steps and baseline algorithm for test or sample type
5) Set up parameter table with ROM derived values of process variables for each step
6) Verify that ROM process variables are within established algorithm limits for each variable
7) Execute slide processing steps with parameters specified in ROM
8) Repeat from step #1 for additional samples

Illustration of liquid-based cytology filter with barcode:



51, 52

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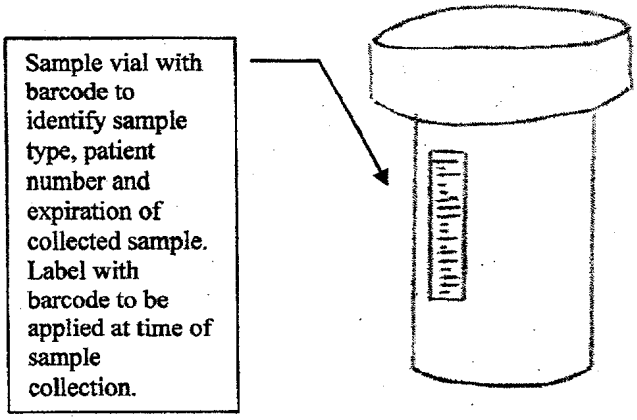
Illustration of liquid-based cytology sample vial with barcode:



54 21 43

ALTERNATE EMBODIMENTS

Please describe any alternate embodiments of your idea/invention addressing the following points: Designs, applications, materials, coatings, uses, accessories, construction processes, costs, etc. Put yourself in the competitor' s shoes and try to identify any alternate ways you could achieve the same results as the exemplary embodiment described above.

ALTERNATE DESIGNS 37

- Multiple options for mechanical interface between ROM and slide processor.
- Instead of pre-determined locations for different filters in tray,
  - The ROM chip could include a map of the different filter locations in the tray, or
  - The slide processor could have means to search for and find the correct filter for a different type of test
  - There could be different tray slots for different filter types, each with a ROM interface 40
- Barcodes on filters and sample vials could be 2 dimensional or 1 dimensional 54

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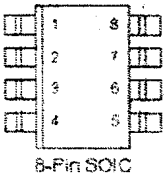
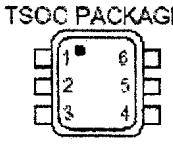
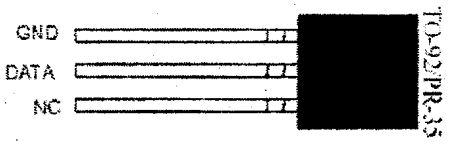
ALTERNATE COMPONENTS

- Multiple options for ROM chips including other 2 terminal devices or other memory chips in conventional IC packages, including:







- Multiple options for custom packaging of alternate ROM chip components

ALTERNATE MATERIALS / COATINGS

- Filter barcodes could be a label or printed directly on to vial 40
- Sample vial barcodes should be applied by label at time of sample collection 54

ALTERNATE APPLICATIONS

OTHER

Attach any supplementary information, including laboratory data, notes, literature, additional figures, etc. that may be relevant to your idea